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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Tina Rauk Bergstrom

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EXAMINER

NICHOLSON, KERI JESSICA

ART UNIT

PAPER NUMBER

4153

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,964	Applicant(s) RAUK BERGSTROM ET AL.	
	Examiner KERI J. NICHOLSON	Art Unit 4153	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2005/10/19</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because of the use of the legal term "comprising" in lines 2 and 6. Correction is required. See MPEP § 608.01(b).

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they *do not include* the reference character sheet 1' that *is* mentioned in the description and they *do include* the reference characters 2', 3', and 4' that *are not* mentioned in the description. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet,

even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 2, and 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "or the like" renders the claims indefinite because the claims include elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claims unascertainable. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Canty (U.S. Patent No. 4,323,062).

8. Regarding claim 1, Canty discloses a surgical drape comprising:
an opening (19/28) intended to be arranged around an operating site on a patient forming a barrier between the operating site and that part of the patient's body lying outside the operating site (column3, lines 23-25); and
at least one member (flaps, 38/44) capable of receiving and/or securing sutures (tubing) without damaging or destroying the barrier between the operating site and the patient's body (column 4, lines 2-7).

9. Regarding claim 2, Canty discloses that the members (flaps, 38/44) are arranged on at least two sides of the opening in such a way that the flow of fluid from the operation site is not impeded (Fig. 1).

10. Regarding claim 5, Canty discloses that the members are upwardly projecting folds in the drape (Fig. 1).

11. Claim 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Bayer (U.S. Patent No. 3,561,440).

12. Regarding claim 1, Bayer discloses a surgical drape comprising:
an opening (18) intended to be arranged around an operating site on a patient forming a barrier between the operating site and that part of the patient's body lying outside the operating site (column3, lines 23-25); and

at least one member (adhesive areas, 20/22) capable of receiving and/or securing sutures without damaging or destroying the barrier between the operating site and the patient's body.

13. Regarding claim 4, Bayer discloses that the drape product consists of a surgical sheet (12) with an operation opening (18) and members (adhesive areas, 20/22) capable of receiving and/or securing sutures arranged on both sides of the operation opening (Fig. 3).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 3 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Canty as applied to claims 1 and 2 above in view of Kelly (U.S. Patent No. 3,916,887). Canty discloses the invention substantially as claimed described above but fails to teach that each member is situated at a distance of 15 – 150 millimeters (\approx 0.6 – 5.9 inches) from the nearest edge of the opening. Kelly discloses a surgical drape comprising members (adhesive strips, 60/60') capable of receiving and/or securing sutures separated from each other by 8.5 inches (215.9 millimeters) defining an operative region (OR) measuring 8 inches (203.2 millimeters) wide (column 6, lines 50-53). Kelly further discloses that the distance between the strips may be varied to suit different

purposes (column 6, lines 57-62). Kelly does not specifically teach the range of distances between the strips and the operative region, however, it would have been obvious to one having ordinary skill in the art to make the surgical drape disclosed by Canty and positioning the suture receiving members within 150 millimeters from the opening to be readily and conveniently available to secure surgical instruments.

16. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bayer as applied to claim 1 above in view of Kelly (U.S. Patent No. 3,916,887). Bayer discloses that the members capable of receiving and/or securing sutures consist of separate material sections secured to a face of the product. However, Bayer fails to teach that the material sections are secured to the top face of the product. Kelly discloses a surgical drape with adhesive on the top surface adjacent to the operative region for attaching various operating room articles (column 2, lines 19-24). It would have been obvious to one having ordinary skill in the art to make the drape disclosed by Bayer with the suture receiving members secured to the top face of the product in order to effectively retain surgical instruments.

17. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bayer in view of Kelly as applied to claims 1 and 6 above and in further view of Scrivens (U.S. Patent No. 4,134,398). Bayer and Kelly disclose the invention substantially as claimed described above but fail to teach that the material sections consist of textile material, nonwoven fabric, plastic film, foam material, or hook-and-loop material. Scrivens discloses a surgical drape (20) comprising a fenestration (30) and a retainer member (40) for securely retaining surgical equipment (Fig. 1, column 3, lines 12-19). Retainer

member (40) is comprised of a flexible material such as plastic, a woven fabric, or a nonwoven fabric (column 4, lines 25-28). It would have been obvious to one having ordinary skill in the art to make the suture securing members of the surgical drape disclosed by Bayer and Kelly of a textile material as taught by Scrivens for many reasons such as manufacturing constraints, cost, etc. Furthermore, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

18. Claims 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayer in view of Kelly as applied to claims 1 and 6 above and in further view of Rothrum et al. (U.S. Patent No. 5,707,703). Bayer and Kelly disclose the invention substantially as claimed described above but fail to teach that a row of separate material sections extend parallel to at least one edge of the opening and fluid is allowed to flow past the row of material sections through intermediate spaces between the material sections. Rothrum discloses a surgical drape (200) comprising a plurality of tube and cable restraints (202) positioned around an opening (204) intermittently (Fig. 7), capable of allowing fluid to flow past the row of restraints. It would have been an obvious matter of design choice to one having ordinary skill in the surgical drape art to make the device disclosed by Bayer and Kelly with the securing members arranged intermittently in rows around the opening as taught by Rothrum for the purpose of allowing fluid to drain from the opening.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KERI J. NICHOLSON whose telephone number is (571)

270-3821. The examiner can normally be reached on Monday - Thursday, 8am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson, can be reached at (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call (800) 786-9199 (IN USA OR CANADA) or (571) 272-1000.

KJN
/K. J. N./
Examiner, Art Unit 4153
2008/02/25

/Gary Jackson/
Supervisory Patent Examiner
Art Unit 4153